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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,448

11/28/2006

Paul Adriaan Van Der Schaaf

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,448	<b>Applicant(s)</b> VAN DER SCHAAF ET AL.	
	<b>Examiner</b> SHAWQUIA YOUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 9-36, 43 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-8 is/are allowed.
- 6) ☒ Claim(s) 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/7/06</u> .                                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 1-40, 43 and 44 are currently pending in the instant application. Claims 5-8 are allowed; claims 37-40 are rejected and claims 1-4, 9-36, 43 and 44 are withdrawn from consideration.

### **I. *Priority***

The instant application is a 371 of PCT/EP05/00034, filed on January 5, 2005 which claims benefit of US Provisional Application 60/535,674, filed on January 9, 2004 and claims benefit of Foreign Application EPO 04100053.0, filed on January 9, 2004.

### **II. *Information Disclosure Statement***

The information disclosure statement (IDS) submitted on July 7, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### **III. *Restriction/Election***

#### ***A. Election: Applicant's Response***

Applicants' election with traverse of Group II in the reply filed on April 1, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Examiner has withdrawn the restriction between Group II and claims 37-40, which are drawn to a composition comprising crystalline polymorphic form B.

Subject matter not encompassed by elected Group II and claims 37-40 are

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withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

#### **IV. Rejections**

##### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup>***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,

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5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, the claims are drawn to a pharmaceutical composition comprising an effective amount of a crystalline polymorphic form B.

### ***The nature of the invention***

A pharmaceutical composition comprising an effective amount of crystalline polymorphic form B.

### ***The state of the prior art***

The state of the prior art is that the preparation of pharmaceutical compositions requires creating solutions, milling, adding diluents, excipients, surfactants, etc. The process of preparing a pharmaceutical composition will cause a specific crystalline form, if in the metastable state to resort back to the most thermodynamically stable form which is the form with the lowest vapor pressure. Polymorphs tend to convert from less stable to more stable forms (Rouhi, page 32). It is also the state of the prior art that an acceptable carrier for a pharmaceutical formulation can be water. Dissolving a specific crystalline form in water, creating an aqueous solution, would put the compound in its free form and not in a crystalline form with a specific X-ray diffraction pattern. The use of a wrong polymorph of a drug when using an aqueous vehicle may provide a phase conversion from the metastable to stable polymorph (Haleblian et al., page 912).

***The predictability or lack thereof in the art***

The predictability or lack thereof in the art is that a metastable compound will resort back into its most thermodynamically stable form which would have a different X-ray diffraction pattern and also that a solution prepared from a specific crystalline form and water would contain the free form of the compound.

***The amount of direction or guidance present and the presence or absence of working examples***

While the specification has provided processes for the preparation of the crystalline forms D, the specification fails to provide the processes for preparing a pharmaceutical composition and to provide the steps of ensuring that the pharmaceutical compositions will maintain the specific forms as found in the specification and will not resort back to the free form or the most thermodynamically stable form of the compound.

***The breadth of the claims***

A pharmaceutical composition comprising an effective amount of crystalline polymorphic form B.

***The quantity of experimentation needed***

The quantity of experimentation needed is undue. One of ordinary skill in the art, without direction, would be unable to maintain a specific metastable crystalline form upon preparation into a pharmaceutical composition which may require milling or the formation of a solution.

***The level of the skill in the art***

While the level of skill in the art is high, one of skill in the art would be unable to maintain a specific metastable crystalline form upon the preparation of a pharmaceutical composition without direction and guidance which is not found in the instant specification. One of skill in the art would expect the pharmaceutical composition to contain the free form of the compound or the most thermodynamically stable form of the compound.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "Form B" is not descriptive and does not define the polymorph that applicant is claiming. Applicant needs some characterization data (i.e., X-ray powder diffraction pattern) to define the polymorph that is being claimed.

Claims 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 37-40 are drawn to a composition comprising polymorphic form B of rizatriptan but these claims are dependent on a claim

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that is drawn to polymorphic form A only. Claims 37-40 are improperly dependent on a claim that does not embrace the invention of the instant claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by *Sandquiet, et al.* (GB 2315673A). The instant invention claims a pharmaceutical composition comprising an effective amount of crystalline polymorphic form B.

The *Sandquiet, et al.* reference teaches rizatriptan benzoate and pharmaceutical compositions comprising thereof (example 8, page 18 and pages 19-21) and their use in treating migraines. This composition anticipates the composition comprising crystalline polymorphic form B of the instant invention because applicants are claiming a composition which could comprise for example water and dissolving a specific crystalline form in water, creating an aqueous solution, would put the compound in its free form and not in a crystalline form with a specific X-ray diffraction pattern. Therefore, the composition would be identical as taught in the prior art.



## **V. Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/  
Examiner, Art Unit 1626  
/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626